



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20591
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,409	12/11/2000	James Martin Lenhard	1430-257	3502

7590 07/30/2002

GLAXO WELLCOME INC.
CORPORATE INTELLECTUAL PROPERTY
FIVE MOORE DRIVE
P.O. BOX 13398
REASEARCH TRIANGLE PARK, NC 27709

EXAMINER

HINES, JANA A

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 07/30/2002 //

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
09/700,409	LENHARD ET AL.	
Examiner	Art Unit	
Ja-Na A Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 58-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s), _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in Paper No. 10 is acknowledged.
2. Claims 58-71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected claims, there being no allowable generic or linking claim. Claims 1-57 are under consideration in the office action.

Drawings

3. New corrected drawings are required in this application, see PTO form 948. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) volunt-

published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 28, 38-39,43, 53-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Lamey (US Patent 5,666,962). Lamey (US Patent 5,666,962) teach thermography as a method of measuring viral activity in a herpes labialis infection. The invention is directed to thermographic imaging as a tool to measure the progress of viral activity in a herpes episode (col. 1 lines 5-10). Thermography of the infected area will demonstrate a significant localized elevation in temperature, treatment with an antiviral agent generally prevents the developing lesion, after successful treatment, the infected individual registers thermographically normal (col. 2 lines 27-36). Antiviral agents are compounds that act in some degree to inhibit the replication of the virus (col. 2 lines 36-38). The technique teaches standardizing a subject; measuring the temperature of the area during one or more stages during the episode (col. 3 lines 1-6). The temperature can be measured before and after the episode and compares the temperatures measured prior, during and after the occurrence (col. 3 lines 17-31). Thermographic imaging can measure temperature changes using an imaging system (col. 3 lines 9-15). Thermographic imaging systems are well known in the art, as are infra-red sensing devices that can evaluate and record temperature changes and such devices provide sensitive results (col. 3 lines 32-47). Infra-red thermography records infra-red radiation at wavelengths between 0.8um and 1mm (col. 3 lines 49-52).

Thus Lamey teach a method of screening a test agent for its ability to cause a thermodynamic change using infrared imaging in a sample measuring; contacting, measuring at specific wavelengths and comparing the differences between the temperatures obtained as claimed by the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-27, 29-30 34-39, 40-42, 44-46, 49-54, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lamey (US Patent 5,666,962) as applied to claims 28 and 43 above, and further in view of Watsuji et al., GB 2,266,182. Lamey (US Patent 5,666,962) has been discussed above, however it does not teach samples comprising organic and inorganic compounds.

Watsuji et al., teach bioelectronic evaluations using biological macromolecules such as proteins, nucleic acids and polysaccharides (page 1 lines 5-8). Detection of changes in the physical or chemical microenvironments can be analyzed (page 2 lines 20-24). It is known that proteins can exhibit temperature changes which can occur over sometimes short periods of time (page 4 lines 1-3). The affinity of the protein for ligands can also be affected by its temperature (page 4-5 lines 25-2). Moreover, nucleic acids are also affected by temperature (page 5 lines 8-15). Thus monitoring the variations in

the intrinsic properties of the macromolecules or ligand is taught, including infrared spectroscopy (page 11 lines 2-5).

Therefore, it would have been prima facie obvious at the time of applicants invention to modify the method of screening a test agent for its ability to cause a thermodynamic change wherein the modification incorporates samples comprised of organic compounds as taught by Watsuji et al. One would have a reasonable expectation of success in employing the sample modification since Watsuji et al., teach that using infrared technology to detect temperature changes in the sample. No more than reasonable skill would have been required to use well known infrared technology to screen and compare samples when the prior art already teaches the sensitive temperature detection abilities of infrared thermographic imaging when the use of alternative infrared thermography techniques is known to distinguish temperature in samples.

7. Claims 31-33, 41-42, 47-48, 55-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lamey (US Patent 5,666,962) and Watsuji et al., (GB 2,266,182) as applied to claims 28 and 43 above, and further in view of Adachi et al, (US Patent 5,445,157). Lamey (US Patent 5,666,962) and Watsuji (GB 2,266,182) have been discussed above, however it does not teach samples comprising mammalian tumor cells.

Adachi et al., (US Patent 5,445,157) teach that it is well known that the temperature of abnormal cells such as cancer cells is a little higher than that of normal cells, an early cancer, a malignant tumor, and can be discovered by detecting a

temperature distribution in the body cavity (col. 1 lines 19-25). The present invention converts the infrared image and detects thermographic variations (col. 1 lines 50-63).

Therefore, it would have been prima facie obvious at the time of applicants invention to modify the method of screening a test agent for its ability to cause a thermodynamic change wherein the modification incorporates samples comprised of tumor cells as taught by Adachi et al. One would have a reasonable expectation of success in employing the sample modification since Adachi et al., teach that using infrared technology to detect temperature changes in the tumor cells since tumor cells are known to be at a higher temperature than normal cells. No more than reasonable skill would have been required to use well known infrared technology to screen and compare mammalian tumor cell samples when the prior art already teach the infrared temperature detection of tumor cell samples.


Prior Art


8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Patent application publication US 2001/0046471 A1 teaches a method for measuring a thermodynamic change in an area of interest. Meyers et al., (US Patent Re. 30,446) teach detecting temperature variations in tissue using infra-red thermography. Sheffield (US Patent 5,356,217) teaches thermal analysis systems and methods for detection and quantitative measurements of enthalpy changes. Wokciechowowski et al., (US Patent 5,340,745) teach a method for the rapid collection of kinetic data from a temperature scanning reactor.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na A Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines
July 29, 2002 


MARK NAVARRO
PRIMARY EXAMINER